DEPARTMENT OF HEALTH AND HUMAN SERVICE

14724

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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June 27, 2001

WARNING LETTER NO. 2001-NOL-32

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Adam J. Johnson, Owner
Bayou Land Seafood, LLC
1008 Vincent Berard Road
Breaux Bridge, Louisiana 70517

Dear Mr. Johnson:

We inspected your firm, located at 1008 Vincent Berard Road, Breaux Bridge, Louisiana, on April 10 through 23, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations cause your vacuum packed crawfish tail meat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The following deviations were documented:

- You must implement a record keeping system in your HACCP plan to comply with 21 CFR 123.6(b)(7). However, your firm did not record monitoring observations at the distribution critical control point to control pathogenic growth as listed in your HACCP plan.

- You must implement the record system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record the internal temperature of the crawfish at the peeling and packing critical control points to control pathogenic growth as listed in your HACCP plan.

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of recording the observed internal cooked crawfish temperatures and observed cooking times at the boiling critical control point to control pathogenic growth as listed in your HACCP plan. In addition, your firm did not follow the monitoring procedures of recording the observed packing times at the packing critical control point to control pathogenic growth as listed in your HACCP plan.

In addition, the investigator documented numerous insanitary conditions that cause the crawfish tail meat products you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act. They are adulterated because they have been prepared, packed, or held under conditions whereby they may become contaminated with filth.

- Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against cross contamination from unclean objects. For example:

  1. They contacted insanitary equipment and then handled cooked crawfish without washing or sanitizing their hands; and,

  2. Their unsanitized clothing came in direct contact with the cooked crawfish.

- Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated within the meaning of the Act. For example, the crawfish transport container contacted the floor and then routinely contacted cooked product. The cooked crawfish are cooled in a chill tank that is encrusted with black and yellow residues.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plan, temperature monitoring records or other useful information that would assist us in evaluating the corrections. If all the corrections cannot be completed before you respond, please explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Richard D. Debo
Acting District Director
New Orleans District

Enclosure: Form FDA 483